

Message

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**From:** Monika Szablicka [monika.szablicka@envigo.com]  
**Sent:** 9/11/2017 4:30:20 PM  
**To:** Odusote, Gloria [odusote.gloria@epa.gov]  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you for your prompt reply and kind words.

I will ask the original submitter to update this information. I believe if I do this I will have to provide the substantiation information but as you said my "hands are tied for now"...

Thank you for your patience and support with this case.

Kindest regards

Monika

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**From:** Odusote, Gloria [mailto:odusote.gloria@epa.gov]  
**Sent:** Monday, September 11, 2017 5:24 PM  
**To:** Monika Szablicka <monika.szablicka@envigo.com>  
**Subject:** RE: Concerning Your Case

Hi Monika,

I'm sorry to hear that. It was a pleasure working with you on this case.

Before I can work with a new consulting company, I need the PMN to be updated with the technical contact from the new company. This would need to be done through CDX.

Best,  
Gloria

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**From:** Monika Szablicka [mailto:monika.szablicka@envigo.com]  
**Sent:** Monday, September 11, 2017 12:11 PM  
**To:** Odusote, Gloria <odusote.gloria@epa.gov>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you for your kind message. However the further communication regarding this case may come from another consulting company now not from Envigo. I have been told that you will be made aware that the new consulting company is taking over work on this case. The new company is based in US therefore it is more convenient for our client.

Please can you let me know if I need to submit anything via CDX with respect to this change?

Thank you.

Kind regards  
Monika

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**From:** Odusote, Gloria [mailto:odusote.gloria@epa.gov]  
**Sent:** Wednesday, September 06, 2017 10:44 PM

**To:** Monika Szablicka <[monika.szablicka@envigo.com](mailto:monika.szablicka@envigo.com)>

**Subject:** RE: Concerning Your Case

Hi Monika,

I put in the 15 day suspension. If you could work towards putting in the suspension through CDX, that would be best but if your hands are tied for now, I can wait.

Best,  
Gloria

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]

**Sent:** Tuesday, September 5, 2017 11:09 AM

**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>

**Subject:** RE: Concerning Your Case

Dear Gloria,

I am sorry it takes long to send the request via CDX for the latest suspension but as it is required now to provide substantiation for each CBI claim I have to wait for my client to provide me his responses. I am afraid that the system will not let me send the Support form until I have the substantiation document.

Is this acceptable please?

Thank you.  
Kind regards  
Monika

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

**Sent:** Friday, August 18, 2017 5:52 PM

**To:** Monika Szablicka <[monika.szablicka@envigo.com](mailto:monika.szablicka@envigo.com)>

**Subject:** RE: Concerning Your Case

Hi Monika,

Thank you for the update and I will wait until you have more information.

Also, management is asking that new information including requests for suspension past 15 days be sent through CDX, so please enter the suspension through CDX. It can be as long as you need it to be and I can rescind the suspension days if something changes on the company's end.

Best,  
Gloria

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]

**Sent:** Friday, August 18, 2017 6:37 AM

**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>

**Cc:** Melissa Elliott <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>

**Subject:** RE: Concerning Your Case

Dear Gloria,

I believe that Melissa has contacted you while I was on vacation.

This is to confirm in writing that our client asked for another 30 days suspension for this case. I have yet not received further explanation as to why they need more time.

As soon as I know more I will let you know.

Thank you.

Best regards

Monika

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**From:** Monika Szablicka

**Sent:** Tuesday, July 25, 2017 5:32 PM

**To:** 'Odusote, Gloria' <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>

**Subject:** RE: Concerning Your Case

Dear Gloria,

I tried calling you but I understand that you are not available. I have informed the company about the July deadline and asked them to provide such explanation.

Hopefully they will come back to me soon.

Thank you.

Kind regards

Monika

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

**Sent:** Tuesday, July 25, 2017 2:52 PM

**To:** Monika Szablicka <[monika.szablicka@envigo.com](mailto:monika.szablicka@envigo.com)>

**Subject:** RE: Concerning Your Case

Hi Monika,

If you have a chance, can you please call me today? The EPA has a July deadline and they are asking for a more in-depth reason for suspensions past the end of July.

Best regards,

Gloria

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]

**Sent:** Friday, July 21, 2017 11:34 AM

**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>

**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you very much for your reply. Please can you let me know when the suspension will end?

Also please note that I was successful today could communicate with Mr. Jeff Bauer directly for our polymer case.

With kindest regards

Monika

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

**Sent:** Thursday, July 20, 2017 10:33 PM

**To:** Monika Szablicka <[monika.szablicka@envigo.com](mailto:monika.szablicka@envigo.com)>

**Subject:** RE: Concerning Your Case

Hi Monika,

Good to know. I'll put you down for another 15-day suspension. It may be easier to do the testing than to completely eliminate exposure for this case. If you have any questions, feel free to call.

I will ask the Program Manager again.

Best,  
Gloria

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]

**Sent:** Thursday, July 20, 2017 4:06 PM

**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>

**Subject:** RE: Concerning Your Case

Dear Gloria,

This is just a quick update to let you know that our client is still looking into the uses.

Meanwhile please can I ask you to contact the Program Manager at EPA, for our polymer case as we have not had any update for a while.

I would really appreciate this.

Thank you.

Kind regards  
Monika

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

**Sent:** 30 June 2017 21:36

**To:** Monika Szablicka

**Subject:** RE: Concerning Your Case

Hi Monika,

The suspension is ending on Thursday July 6<sup>th</sup>. Do you think you'll have an update by then?

Best,  
Gloria

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]

**Sent:** Friday, June 30, 2017 12:42 PM

**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>

**Cc:** Melissa Elliott <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>; David Howes <[david.howes@envigo.com](mailto:david.howes@envigo.com)>

**Subject:** RE: Concerning Your Case

Dear Gloria,

I am still waiting for our client to respond to your comments. Please can you let me know when is the suspension ending?

Additionally we are having difficulties contacting the Program Manager for our polymer case (p-16-0509). Please would it be possible for you to contact him for an update on our case? This would be highly appreciated.

Thank you.

Kind regards

Monika

Monika Szablicka  
Regulatory Specialist  
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F +44 (0) 1480 892 362  
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**From:** Monika Szablicka  
**Sent:** Thursday, June 22, 2017 5:38 PM  
**To:** 'Odusote, Gloria'  
**Cc:** Melissa Elliott; David Howes  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you for your comment. Is there any other information the company can provide please?

Kind regards

Monika

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** 22 June 2017 17:21  
**To:** Monika Szablicka  
**Cc:** Melissa Elliott; David Howes  
**Subject:** RE: Concerning Your Case

Hi Monika,

I am still seeing the inhalation exposure during the cleaning process, which is what we had assessed. Also, in the report we did estimate some removal due to activated sludge treatment and we still assessed some of the chemical getting into the drinking water.

Best,  
Gloria

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Thursday, June 22, 2017 10:31 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Cc:** Melissa Elliott <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>; David Howes <[david.howes@envigo.com](mailto:david.howes@envigo.com)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Our client has sent us some update. They confirm that all industrial process occur in a closed-system and residual monomer in waste water is treated by the activated sludge method and discharged.  
Please can you refer to the revised document attached?

Please can you let me know if this update is sufficient for you to proceed?

Thank you.

Kind regards

Monika

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

**Sent:** 22 June 2017 15:10

**To:** David Howes; Monika Szablicka

**Cc:** Melissa Elliott

**Subject:** RE: Concerning Your Case

Hi Monika and David,

Do you have any update about your case? I need an update or a request for suspension by today as I am out of the office tomorrow and the Day 90 is on Sunday.

Best,

Gloria

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**From:** David Howes [<mailto:david.howes@envigo.com>]

**Sent:** Tuesday, June 13, 2017 11:12 AM

**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>; Monika Szablicka <[monika.szablicka@envigo.com](mailto:monika.szablicka@envigo.com)>

**Cc:** Melissa Elliott <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>

**Subject:** RE: Concerning Your Case

Dear Gloria

I have no specific concerns and I am available to call whenever is most convenient to you.

Please let me know when I should call.

Best regards

David

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Expert Consultant  
Regulatory Consulting  
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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

**Sent:** 13 June 2017 13:40

**To:** Monika Szablicka; David Howes

**Cc:** Melissa Elliott

**Subject:** RE: Concerning Your Case

Hi Monica and David,

I cannot make calls outside the U.S but you are free to call me at 202-564-1845. David, do you have specific questions you would like me to answer? I want to make sure that before we talk, I have the answers you need and if I do not, I can get one of the scientists in the phone call as well.

Best,  
Gloria

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Tuesday, June 13, 2017 5:32 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>; David Howes <[david.howes@envigo.com](mailto:david.howes@envigo.com)>  
**Cc:** Melissa Elliott <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Melissa informed me that she agreed to the extension, I think we do not have any other option. I am not in the office today but I have asked my colleague who is our Expert Consultant to discuss with you EPA further concerns regarding the PMN substance exposure. His name is David Howes and he is also included in this correspondence. Please will you be able to contact him at the following number:

+44(0)1480892269. David will be in the office until 5pm UK time.

Thank you.  
Kind regards  
Monika

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** 12 June 2017 14:05  
**To:** Monika Szablicka  
**Subject:** RE: Concerning Your Case

Also, your day 90 is here. Would you like to request a suspension? Also, I was wondering if we could talk about the report you sent.

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Monday, June 12, 2017 1:47 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you for your reply and I am sorry I could not call on Friday as I left my office before I received your message. I am checking with the technical contact who told us about the new person, assigned to our polymer case, at EPA.

Kindest regards  
Monika

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** 09 June 2017 18:15  
**To:** Monika Szablicka  
**Subject:** RE: Concerning Your Case

Hi Monika,

I don't see any reassignments for that case. If you are free, can you please call?

Best,  
Gloria

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]

**Sent:** Friday, June 9, 2017 12:55 PM

**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>

**Cc:** Melissa Elliott <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>

**Subject:** RE: Concerning Your Case

Dear Gloria,

Following on from my email please can I ask you to provide me with contact details for the Program Manager for our polymer case. I have found out from our technical contact that the person has changed again and it is now Gloria Duclate. I would like to send her some information regarding our case.

I thank you in advance for your help.

Kindest regards  
Monika

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**From:** Monika Szablicka

**Sent:** Friday, June 09, 2017 4:27 PM

**To:** 'Odusote, Gloria'

**Subject:** RE: Concerning Your Case

Dear Gloria,

We have obtained the information as per attached. The client confirmed that it does not contain CBI.

Please can you let me know if it is sufficient for the EPA final assessment?

Thank you.

Kindest regards  
Monika

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Thursday, June 08, 2017 10:14 PM  
**To:** Monika Szablicka  
**Subject:** RE: Concerning Your Case

Hi Monika,  
Sure you can but if it's about exposure, I may not have much to tell you.

Best,  
Gloria

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Thursday, June 8, 2017 11:22 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

I have some information from our client. Do you think I could send it to you for your review before I submit this via CDX?

Kind regards  
Monika

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Wednesday, June 07, 2017 4:10 PM  
**To:** Monika Szablicka  
**Subject:** RE: Concerning Your Case

Hi Monika,  
Sorry for the delay in response. I have been out of the office for some time.  
That is the only number I have for him. Have you still not heard from him?

Also do you have any updates about your case with me? The Day 90 is this week.

Best,  
Gloria

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Thursday, May 25, 2017 8:44 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>

**Cc:** Melissa Elliott <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>

**Subject:** RE: Concerning Your Case

Dear Gloria,

I am contacting you again for the P-16-0509 case. Unfortunately I can not get hold of the Program Manager Jeff Bauer via phone. Please can you provide me with his phone number?

Thank you.

Best regards

Monika

Monika Szablicka  
Regulatory Specialist  
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F +44 (0) 1480 892 362  
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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

**Sent:** Tuesday, May 16, 2017 6:55 PM

**To:** Monika Szablicka

**Subject:** RE: Concerning Your Case

Hi Monika,

Jeff Bauer is the Program Manager for your case. I'm not sure when the consent order will be developed especially with the current backlog. His phone number is 202-564-9042.

Best regards,

Gloria

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]

**Sent:** Tuesday, May 16, 2017 9:30 AM

**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>

**Cc:** Melissa Elliott <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>

**Subject:** RE: Concerning Your Case

Dear Gloria,

Would it be possible please for you to contact the Program Manager at EPA Rose Allison, for our other PMN which is related to this submission. It is P-16-0509. We have submitted response to the action letter and we understand that the consent order will be issued by June 5<sup>th</sup>. We have however not heard anything from EPA. Please can you confirm this as I am unable to contact our technical contact at the moment.

I would really appreciate your help regarding this.

Thank you.

Kind regards

Monika

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F +44 (0) 1480 892 362  
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**From:** Monika Szablicka  
**Sent:** Tuesday, May 16, 2017 2:22 PM  
**To:** 'Odusote, Gloria'  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you very much.

Kindest regards  
Monika

Monika Szablicka  
Regulatory Specialist  
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F +44 (0) 1480 892 362  
envigo.com



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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Tuesday, May 16, 2017 1:53 PM  
**To:** Monika Szablicka  
**Subject:** RE: Concerning Your Case

Hi Monika,  
Sure, let me know if there is any way I can help.

Best,  
Gloria

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Tuesday, May 16, 2017 8:39 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Our client has requested today a suspension of 15 days. Please can you let me know if this is acceptable?

Thank you.

Kind regards  
Monika

Monika Szablicka  
Regulatory Specialist  
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F +44 (0) 1480 892 362  
envigo.com



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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Friday, May 12, 2017 6:58 PM  
**To:** Monika Szablicka  
**Subject:** RE: Concerning Your Case

Hi Monika,  
Please let me know if I misunderstood you but I took your previous message as you asking for a 7 day suspension. Please let me know if that is not the client's request and I can rescind the suspension.

Best regards,  
Gloria

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**From:** Monika Szablicka [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Friday, May 12, 2017 12:39 PM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Cc:** Melissa Elliott <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you very much for your confirmation. I have asked if this data is available. I will keep you updated.

With very best regards  
Monika

Monika Szablicka  
Regulatory Specialist  
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F +44 (0) 1480 892 362  
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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Thursday, May 11, 2017 6:58 PM  
**To:** Szablicka, Monika  
**Subject:** RE: Concerning Your Case

Hi Monika,  
A week should be fine, if they think they have monitoring data or equipment information detailing the exposures. I can let you know if you'll need to request another suspension.

Best,  
Gloria

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**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]

**Sent:** Thursday, May 11, 2017 10:27 AM

**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>

**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you for contacting me. I am sorry I am not in the office today.

Today our client informed me that they will be preparing the additional information regarding no inhalation and environmental exposure. They will however need about a week for this. Will this be acceptable to EPA please?

Thank you.

Kind regards

Monika

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

**Sent:** 11 May 2017 15:06

**To:** Szablicka, Monika

**Subject:** RE: Concerning Your Case

Hi Monika,

Do you want to call? I am not sure what kind of information the company might want to resubmit and I might be able to give better advice if we deal with the specifics.

Best regards,

Gloria

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**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]

**Sent:** Wednesday, May 10, 2017 11:56 AM

**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>

**Subject:** RE: Concerning Your Case

Dear Gloria,

Our client is preparing the final response however they asked me to confirm with you the following:

If they decide to select Option 3 from the action letter and withdraw the PMN how soon they can re-submit? They are considering changing some information provided in the original PMN. This is very hard decision for them.

Please can you advise?

Thank you.

Kind regards

Monika

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Regulatory Specialist  
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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Monday, May 08, 2017 7:35 PM  
**To:** Szablicka, Monika  
**Subject:** RE: Concerning Your Case

Hi Monika,

If you provide information that there is no inhalation and environmental exposures, the testing would no longer be upfront.

You would still need to respond to the action letter, checking the option that you are providing more information and giving us the time to review the information and write the consent order.

Best,  
Gloria

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**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Monday, May 8, 2017 10:14 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you very much for your time earlier on. There was one question which I would appreciate you clarification on. If we provide an information that there is no inhalation possibility - would we still need to conduct the studies (OECD 422 and OECD 486)? Would we still have to respond to the action letter?

Thank you  
Kind regards  
Monika  
Monika Szablicka  
Regulatory Specialist  
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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Monday, May 08, 2017 1:31 PM  
**To:** Szablicka, Monika  
**Subject:** RE: Concerning Your Case

Hi Monika,  
I'm free today. Feel free to call anytime.

Best regards,  
Gloria

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**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Monday, May 8, 2017 8:23 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Cc:** Elliott, Melissa <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Please can you let me know if you are available for the call today?

Thank you.

Kind regards

Monika

Monika Szablicka

Regulatory Specialist

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**From:** Szablicka, Monika

**Sent:** Friday, May 05, 2017 9:49 AM

**To:** 'Odusote, Gloria'

**Cc:** Elliott, Melissa

**Subject:** RE: Concerning Your Case

Dear Gloria,

Please can you let me know when it will be convenient for you so I can call you?

I will be in a meeting until 11am UK time and then between 12.30-14.00pm UK time.

Thank you.

Kind regards

Monika

Monika Szablicka

Regulatory Specialist

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

**Sent:** Thursday, May 04, 2017 7:29 PM

**To:** Szablicka, Monika

**Cc:** Elliott, Melissa

**Subject:** RE: Concerning Your Case

Hi Monica,

In answering this, I would have to explain the test. Since that is CBI, it would probably be best to explain this over the phone.

Best regards,

Gloria

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**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]

**Sent:** Thursday, May 4, 2017 11:43 AM

**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>

**Cc:** Elliott, Melissa <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>

**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you for your kind assistance. Our client is considering the regulatory options and they have some queries. Please can you help us understanding the engineering report, i.e. is there a specific part which we should pay attention to?

In the EPA action letter it is stated that there is a concern for acute toxicity however we have submitted the test report on acute toxicity (please refer to Attachment no. 12 in the original PMN). Additionally, and also as stated in the engineering report the compound does not raise concerns regarding mutagenicity or genetic toxicity in vivo and is unlikely to be carcinogenic. We would really appreciate if you could give us more details as to why the OECD 422 and OECD 486 are required?

Our client is also considering an analog substance which could possess any data on the health effects information but it is difficult to identify the appropriate analog.

Another question which our client has is whether we can change the application without selecting these 3 options?

Please can you give us your comments regarding the above?

Thank you.

Kind regards  
Monika

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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

**Sent:** 27 April 2017 18:09

**To:** Szablicka, Monika

**Cc:** Elliott, Melissa

**Subject:** RE: Concerning Your Case

Hi Monika and Melissa,

Yes, you still have the current suspension and since we have been talking, the suspension applies to the action letter as well. Please let me know if there is any way that I can help speed up the process. With the current changes in the EPA, wrapping up the review time for these chemicals has become a priority.

Best regards,  
Gloria Odusote

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**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]

**Sent:** Wednesday, April 26, 2017 7:33 AM

**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>; Elliott, Melissa <[melissa.elliott@envigo.com](mailto:melissa.elliott@envigo.com)>

**Subject:** RE: Concerning Your Case

**Importance:** High

Dear Gloria,



I am aware about the two separate 15 day suspensions to allow us for any review and actions from the engineering report. However I think the 30 days response to the EPA action letter (dated Mar27, 2017) ends today please can you therefore confirm that the extension also applies to this? Unfortunately our client is still considering their final decision.

I appreciate your response at your earliest convenience.  
Thank you.

Kind regards  
Monika

Monika Szablicka  
Regulatory Specialist  
T +44 (0) 1480 892 439  
F +44 (0) 1480 892 362  
envigo.com



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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Wednesday, April 12, 2017 1:56 PM  
**To:** Szablicka, Monika  
**Subject:** RE: Concerning Your Case

Hi Monica,  
Do you have the fax number yet? Also your day 90 is coming up. Would you like to request a suspension while you read through the report and come up with the new information?

Bets regards,  
Gloria

---

**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Wednesday, April 5, 2017 10:15 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

I am sorry for this. I am checking with the technical contact if the fax number is available at her side.

Thank you.

Kind regards  
Monika

Monika Szablicka  
Regulatory Specialist  
T +44 (0) 1480 892 439  
F +44 (0) 1480 892 362  
envigo.com



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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Tuesday, April 04, 2017 9:14 PM  
**To:** Szablicka, Monika  
**Subject:** RE: Concerning Your Case

Hi Monica,  
I hope this email finds you well. I have the engineering report for your case. Do you have a domestic fax number?

Best regards,  
Gloria

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**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Tuesday, March 28, 2017 10:46 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you very much for contacting me with respect to our submission.

I will summarize your concerns with regards to the substance and will inform our client respectively while waiting for the official EPA letter.

If I understood correctly, may I request the engineering controls report to be sent to us via fax?  
The number for the fax is: (0044)01480 892362.

Thank you.  
Kind regards  
Monika  
Monika Szablicka  
Regulatory Specialist  
T +44 (0) 1480 892 439  
F +44 (0) 1480 892 362  
[envigo.com](http://envigo.com)



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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Tuesday, March 28, 2017 2:09 PM  
**To:** Szablicka, Monika  
**Subject:** RE: Concerning Your Case

Hi Monica,  
Can you please call me again. Another submitter called me right before you called.

Best regards,  
Gloria

---

**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Tuesday, March 28, 2017 4:50 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Subject:** RE: Concerning Your Case

Dear Gloria,

Thank you for your reply. Yes I will call you at 9am EST (2pm UK time).

Kind regards  
Monika

Monika Szablicka  
Regulatory Specialist  
T +44 (0) 1480 892 439  
F +44 (0) 1480 892 362  
envigo.com



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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Monday, March 27, 2017 9:01 PM  
**To:** Szablicka, Monika  
**Subject:** RE: Concerning Your Case

Hi Monica,  
I know it is very late your time. Would you be free to talk tomorrow at 9am EST to talk about your case. Unfortunately, I can't list the PMN number in an email to you as that is CBI.

Best regards,  
Gloria

---

**From:** Szablicka, Monika [<mailto:monika.szablicka@envigo.com>]  
**Sent:** Monday, March 27, 2017 11:58 AM  
**To:** Odusote, Gloria <[odusote.gloria@epa.gov](mailto:odusote.gloria@epa.gov)>  
**Subject:** RE: Concerning Your Case

Dear Ms Odusote,

Thank you for contacting me. I have tried to calling you just now but I understand that you were not available. Please can you let me know which case number you were referring to in your email?

Thank you  
Kind regards  
Monika  
Monika Szablicka  
Regulatory Specialist  
T +44 (0) 1480 892 439  
F +44 (0) 1480 892 362  
envigo.com



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**From:** Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]  
**Sent:** Monday, March 27, 2017 3:31 PM  
**To:** Szablicka, Monika  
**Subject:** EPA: Concerning Your Case

Hi Ms. Szablicka,

My name is Gloria Odusote and I am the Program Manager for your case. I would like to give you an update on your case.

Please call me at the number below at your earliest convenience.

Best regards,  
Gloria Odusote

Gloria Odusote  
Chemical Control Division  
EPA East  
1200 Pennsylvania Ave. NW  
Room 4133G, Mail Code 7405M  
Washington, DC 20460  
202 564-1845  
Fax 202 564 9490

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